

UTAH MEDICAL
PRODUCTS INC.

FEB 10 1997

510(k) Summary

November 8, 1996

Trade Name: Liberty Rectal Pelvic Floor Exerciser
Common Name: Electrical Pelvic Floor Stimulation System
Classification: Nonimplanted Electrical Continence Device. 21 CFR §876.5320

The Utah Medical Products, Inc. (UMP) Liberty Rectal Pelvic Floor Exerciser (PFS-043) is substantially equivalent to the UMP Liberty Probe (PFS-041), cleared for marketing under K960496, and to the Hollister InCare Anal Applicator (ICAA), cleared for marketing under K891773.

The device consists of an injection molded thermoplastic applicator that supports two stainless steel electrode rings that apply electrical stimulation to a patient in order to help train neuromuscular tissue in the pelvic floor for improvement or restoration of urinary continence in men and women. The electrical stimulation energy is conducted to the electrodes via a two conductor cable and connector that plugs into the Liberty Stimulator.

The PFS-043 is indicated for use to help train the pelvic floor muscles using electrical stimulation. The PFS-043 is a rectal applicator that is used with the UMP Liberty PFS System (PFS), which is a battery powered electrostimulation device that applies electrical stimulation through electrodes on the applicator.

The technological characteristics of the UMP PFS-043 probe are substantially equivalent to the UMP PFS-041 probe and the ICAA applicator. There are differences in the size and placement of the stainless steel electrodes and in the thermoplastic materials used to mold the applicators, however, the PFS-043 probe and the ICAA applicator both utilize a single electrode pair with equivalent anatomical placement. The new device and the predicate devices are all manufactured using biocompatible materials.

Laboratory tests of the UMP PFS-043 probe and the ICAA applicator demonstrated that they provide equivalent electrical stimulation of the pelvic floor muscles.

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